

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE



In re Patent Application of:
Rowe et al.

Patent Application No.: 10/614,546

Date Filed: July 3, 2003

For: APPARATUS AND METHOD FOR
PACKAGING ELONGATE
SURGICAL DEVICES

Examiner: Fidei, David
Art Group: 3728

DECLARATION OF LONG-FELT NEED

1. My name is Mark Ashby.
2. I am the Principal of ASHBY CONSULTING, and have over 16 years of experience in the medical device industry, including positions as Vice President/General Manager at Applied Medical Resources and Vice President R&D at Sub-Q, Inc. I have extensive experience with the development, manufacturing and distribution of elongate medical devices utilizing coiled medical packaging.
3. For a long time now, and at least as early as 1990, there has been a long-felt need in the medical device industry for a coiled dispenser package without clips.
4. The problems associated with prior art coiled packages having clips include: limited coil stability and compromised coil integrity in storage/shipping/handling, putting the medical device contained within at risk of mechanical damage and/or

compromised sterility due to pouch damage; increased number and size of supplemental components to compensate for limited coil stability, such as cards, trays, increased size/strength of pouch, increased external packaging; added coil bulk because adjacent coil loops are necessarily separated by clip structure; added manufacturing cost of the clips and the necessary coil-to-clip assembly; surface irregularities on coil-profile due to clip projections, which put product at risk for compromised sterility due to pouch damage as well as adding bulk.

5. The clipless coiled medical packages offered by Clean Cut Technologies, LLC satisfy the long-felt need in the medical industry by providing a package for elongate medical and surgical devices with coiled tubes which are thermally bonded together. The curved thermal welds between the coiled portions cause the coiled portions to be fixed together in a non-peelable relationship without use of additional adhesive materials and without need for clips. The thermal welds cause adjacent surfaces of common thermoplastic material to plasticize and conjoin. This is of particular benefit for coiled medical packages, which utilize materials of high rigidity and low surface friction such as polyethylene, because thermal welding uniquely provides a secure non-peelable attachment that shares the physical properties, biocompatibility, and environment stability of any chosen thermoplastic coil tubing. Further benefit is that thermal bonding is accomplished without the inclusion, handling, and expense associated with the use of adhesives, external mechanical stabilizing structures, or complex interlocking tube profiles.

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Art Unit 3728
Declaration of Long-Felt Need
Attorney Docket No. CCT1.PAU.01 (formerly 6228-A)

Patent Application

The undersigned, being hereby warned that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001, and that such willful false statements may jeopardize the validity of the application or any resulting registration, declares that the facts set forth in this declaration are true; all statements made of his own knowledge are true; and all statements made on information and belief are believed to be true.

Date: 1-31-07

Mark Ashby
Name: MARK ASHBY
Title: PRINCIPAL
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